



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Submitted for form 1449/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/785,681	
Filing Date	February 24, 2004	
First Named Inventor	Montalto <i>et al.</i>	
Group Art Unit	Unassigned 1653	
Examiner	Unassigned CARLSON	
Attorney Docket Number	07595.105001 SER CON Prions	

3499735\_1.DOC

## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages / Relevant Figures Appear
		Number	Kind Code (if known)			
ICC	AA	3,112,249	A	Toulmin	11-26-1963	
	AB	4,290,774	A	Girgis <i>et al.</i>	09-22-1981	
ICC	AC	4,762,792	A	Girgis <i>et al.</i>	08-09-1988	
	AD	5,633,349	A	Reichl	05-27-1997	
	AE	5,756,678	A	Shenoy <i>et al.</i>	05-26-1998	
ICC	AF	2003/0032780	A1	Montalto <i>et al.</i>	02-13-2003	

## FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office	Number	Kind Code <sup>4</sup> (if known)				
ICC	AG	EP	0 742 018	A2	Collagen Corp.	11-13-1996		
	AH	EP	0 937 735	A	Rotkreuzstiftung	08-25-1999		
ICC	AI	WO	02/090379	A1	Serologicals Royalty Co.	11-14-2002		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
ICC	AI	APPEL, T.R., <i>et al.</i> "Heat stability of prion rods and recombinant prion protein in water, lipid and lipid-water mixtures", <i>J. General Virol.</i> 82:465-473 (2001).	
	AJ	BROWN, P., <i>et al.</i> "Newer data on the inactivation of scrapie virus or Creutzfeldt-Jakob disease virus in brain tissue", <i>J. Infect. Dis.</i> , 153(6):1145-1148 (June 1986).	
	AK	BROWN, P., <i>et al.</i> , "The distribution of infectivity in blood components and plasma derivatives in experimental models of TSE transfusion," <i>Transfusion</i> , 38(9):810-816 (Sept. 1998).	
	AL	DARBORD, J.C., "Inactivation of prions in daily medical practice," <i>Biomed. &amp; Pharmacother.</i> , 53(1):34-38 (1999).	
	AM	DORMONT, D., "Agents that cause transmissible subacute spongiform encephalopathies," <i>Biomed. &amp; Pharmacother.</i> , 53(1):3-8 (1999).	
	AN	ERNST, D.R., and RACE, R.E., "Comparative analysis of scrapie agent inactivation methods," <i>J. Virol. Methods</i> , 41(2):193-201 (February 1993).	
	AO	FOSTER, P.R., <i>et al.</i> , "Studies on the removal of abnormal prion protein by processes used in the manufacture of human plasma products," <i>Vox Sanguinis</i> , 78(2):86-95 (2000).	
ICC	AP	HORWICH, A.L., & WEISSMAN, J.S., "Deadly conformations -- Protein misfolding in prion disease", <i>Cell</i> , 89:499-510 (May 16, 1997).	

Examiner Signature	<i>J C Carlson</i>	Date Considered	9-28-05
--------------------	--------------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Submitted for form 1449/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/785,681
Sheet	2	of	3	Filing Date	February 24, 2004
				First Named Inventor	Montalto <i>et al.</i>
				Group Art Unit	Unassigned
				Examiner	Unassigned
				Attorney Docket Number	07595.105001 SER CON Prions

3499735.I.DOC

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	† e
<i>fcc</i>	BA	MASTERTON, Chemical Principles, 4 <sup>th</sup> Ed. (1997), pp. 450, 451, 457.	
	BB	MORGENTHALER, J.-J., "New developments in plasma fractionation and virus inactivation," <i>Vox Sang.</i> , 78(suppl. 2):217-221 (2000).	
	BC	OESCH, B., <i>et al.</i> , "Application of prionics Western blotting procedure to screen for BSE in cattle regularly slaughtered at Swiss abattoirs," <i>Arch. Virol.</i> , 16:189-195 (2000).	
	BD	PARLIAMENTARY OFFICE OF SCIENCE & TECHNOLOGY, "BSE and CJD: Science, Uncertainty and Risk" <i>POST Technical Report</i> (Parliamentary Office of Science & Technology, London), 78:1-12 (April 1996).	
	BE	PL107-9 FEDERAL INTER-AGENCY WORKING GROUP, "Animal disease risk assessment, prevention and control act of 2001. Final report." (January 2003). Listed at <a href="http://www.bna.com/webwatch/madcow.htm">http://www.bna.com/webwatch/madcow.htm</a> , accessed August, 2003.	
	BF	PRUSINER, S.B., <i>et al.</i> , "Thiocyanate and hydroxyl ions inactivate the scrapie agent," <i>Proc. Natl. Acad. Sci. USA</i> , 78(7):4606-4610 (July 1981).	
	BG	SIMONS, K., & EHEHALT, R., "Cholesterol, lipid rafts and disease", <i>J. Clin. Invest.</i> , 110(5):597-603 (September 2002).	
	BH	TAYLOR, D.M., <i>et al.</i> , "Decontamination studies with the agents of bovine spongiform encephalopathy and scrapie," <i>Arch. Virol.</i> , 139(3-4):313-326 (1994).	
	BI	TAYLOR, D.M., "Inactivation of the BSE Agent," <i>J. Food Safety</i> , 18:265-274 (1998).	
	BJ	TAYLOR, D.M., <i>et al.</i> , "Solvent extraction as an adjunct to rendering: The effect on BSE and scrapie agents of hot solvents followed by dry heat and steam," <i>Vet. Record</i> , 143:6-9 (1998).	
	BK	TAYLOR, D.M., "Inactivation of BSE-Like Agents", <i>USAHA Web-- 2001 USAHA Proceedings: Inactivation of BSE-Like Agents</i> (2001), <a href="http://www.usaha.org/speeches/speech01/s01taylor.html">www.usaha.org/speeches/speech01/s01taylor.html</a> , accessed August 8, 2003.	
	BL	UNIVERSITY OF CALIFORNIA AT SAN DIEGO, "Prion Research Guidelines," accessed April 28, 2004 at <a href="http://www.neurosci.ucsd.edu/Safety_Docs/UCSD_Prion_FactSheet.htm">http://www.neurosci.ucsd.edu/Safety_Docs/UCSD_Prion_FactSheet.htm</a> .	
	BM	Von HOLST, C., <i>et al.</i> , "Determination of an appropriate heat treatment of animal waste using the ELISA technique: Results of a validation study," <i>Meat Science</i> , 54:1-7 (2000).	
	BN	WALKER, S.G., <i>et al.</i> , "Aqueous two-phase partition of complex protein feedstocks derived from brain tissue homogenates," <i>J. Chromatography B</i> , 680:91-96 (1990).	
<i>fcc</i>	BO	WORLD HEALTH ORGANIZATION (WHO), "Public health issues related to animal and human spongiform encephalopathies: Memorandum from a WHO meeting," <i>Bulletin of the World Health Organization</i> , 70(2):183-190 (1992). [Meeting in Geneva, Switzerland, 12-14 November 1991, World Health Organization 1992, WHO/CDS/VPH/92.104, 19 pages.]	

Examiner Signature	<i>McCullar</i>	Date Considered	9-28-05
--------------------	-----------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Submitted for form 1449/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/785,681
Sheet	3	of	3	Filing Date	February 24, 2004
				First Named Inventor	Montalto <i>et al.</i>
				Group Art Unit	Unassigned
				Examiner	Unassigned
				Attorney Docket Number	07595.105001 SER CON Prions

3499735\_1.DOC

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
<i>fcc</i>	BP	Recommendations for Minimizing the Risk of Infection by Agents Causing Zoonoses and Other Animal Infections in the Manufacture of Medicinal Products, Federal Journal of Official Publications (BAnz., Germany), No. 164, p. 6120 (1991). <span style="float: right;">T<sup>6</sup></span>		

Examiner Signature	<i>J C Carlson</i>	Date Considered	9-28-05
--------------------	--------------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

DEC 23 2004

(Use as many sheets as necessary)

Sheet

1

of

1

## Complete if Known

Application Number	10/785,681
Filing Date	February 24, 2004
First Named Inventor	Montalto, Joseph G. et al.
Group Art Unit	1614 1653
Examiner Name	Unassigned CARLSON
Attorney Docket Number	07595.105006

## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
KCC	AA	6,407,212		MORGENTHALER et al	June 18, 2002	

## FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Relevant Figures Appear
		Office	Number	Kind Code <sup>2</sup> (if known)			
KCC	AB	EP	0 937 735 B1		MORGENTHALER et al		
KCC	AC	WO	9941274		MORGENTHALER et al		

Examiner Signature	KCCarlson	Date Considered	9-28-05
--------------------	-----------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.